

(Continued)

Analysis of Carcinogenic Potential in Male Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:10)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CTRL1 CTRL2 LOW MEDIUM HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#--] [---+] [---\*] ^ + \*  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
					IN 79-93	2			
					Tumor rate: <1% in CTL - Total	-		[---*]	[---*]
SKIN	(5700	)TRICHOEPITHEL(570035	)	IN	IN 105-106	1	0.546	0.658	0.658
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
SKIN	(5700	)NEURAL CREST (570036	)	IN	IN 105-106	1	0.378	0.296	0.296
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
SKIN	(5700	)MYXOMA (570041	)	IN	IN 105-106	1	1.000	0.791	0.792
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
SKELETAL M(5800		)MALIGNANT SCH(340007	)	FA	FA 82	1	1.000	0.800	0.800
					FA 82	2			
					Tumor rate: 1% in CTL - Total	-			
BONE/FEMUR(5901		)HISTIOCYTIC S(010010	)	MX	IN 0-78	1	0.667	0.240	0.241
					IN 0-78	2			
					Tumor rate: <1% in CTL - Total	-			
STIFLE JOI(6201		)HISTIOCYTIC S(010010	)	MX	IN 0-78	1	0.667	0.240	0.241
					IN 0-78	2			
					Tumor rate: <1% in CTL - Total	-			
ADIPOSE TI(6400		)HISTIOCYTIC S(010010	)	MX	FA 65	1	0.193	0.037*	0.037*
					FA 65	2			
					Tumor rate: <1% in CTL - Total	-		[---*]	[---*]
ADIPOSE TI(6400		)LIPOSARCOMA ((570018	)	FA	FA 65	1	0.193	0.037*	0.037*
					FA 65	2			
					Tumor rate: <1% in CTL - Total	-		[---*]	[---*]
EYES (6500		)AMELANOTIC ME(650020	)	IN	IN 94-104	1	0.138	0.020+	0.020+
					IN 94-104	2			
					Tumor rate: <1% in CTL - Total	-		[---+]	[---+]
PARANASAL (6700		)SQUAMOUS CELL(090038	)	FA	FA 104	1	0.550	0.657	0.657
					FA 104	2			
					Tumor rate: <1% in CTL - Total	-			
BODY CAVIT(6800		)MESOTHELIOMA (320018	)	IN	IN 105-106	1	0.358	0.223	0.223
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
BODY CAVIT(6800		)PARAGANGLIOMA(680005	)	IN	IN 105-106	1	0.173	0.030*	0.030*
					IN 105-106	2			

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(Continued)

Analysis of Carcinogenic Potential in Male Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend

Run Date & Time: February 26, 1997 (16:10)

Source: c:\arat\xrod.txt

Dose Levels Included: CTRL1 CTRL2 LOW MEDIUM HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols {^---} {-#--} [--+-] [---\*] ^ % + \*

Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
		Tumor rate: <1% in CTL - Total			-		{---*}	{---*}
BODY CAVIT(6800		JOSSIFIED SARC(6800007		FA FA 105	1	0.173	0.030*	0.030*
				FA 105	2			
		Tumor rate: <1% in CTL - Total			-		{---*}	{---*}

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# **Test of Dose-Response Positive Linear Trend in Female Rats**

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Ted Guo, PH.D, CDER/FDA

Run Date & Time: February 26, 1997 (16:51)

Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#---] [---+] [---\*] ^ # + \*  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<.005 P<.01 P<.025 P<.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
BRAIN	(0100)	)OLIGODENDROGL	(010004)	) FA	FA 85	1	0.596	0.683	0.683
					FA 85	2			
					Tumor rate: <1% in CTL - Total	-			
BRAIN	(0100)	)GRANULAR CELL	(010005)	) IN	IN 79-93	1	0.238	0.205	0.205
					IN 79-93	2			
					IN 105-106	1			
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
NASAL CAVI	(0602)	)ADENOMA, PAPI	(060207)	) IN	IN 105-106	1	0.393	0.325	0.325
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
LUNGS	(0900)	)ALVEOLAR/BRON	(090016)	) IN	IN 105-106	1	0.675	0.745	0.746
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
LUNGS	(0900)	)SQUAMOUS CELL	(090038)	) MX	IN 105-106	1	1.000	0.805	0.805
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
ORAL CAVIT	(1000)	)SQUAMOUS CELL	(090038)	) MX	IN 94-104	1	0.348	0.111	0.111
					IN 94-104	2			
					Tumor rate: <1% in CTL - Total	-			
ORAL CAVIT	(1000)	)DENTINOMA, UN	(100003)	) IN	IN 105-106	1	0.199	0.039*	0.039*
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total	-			
LIVER	(1800)	)HEPATOCELLULA	(180031)	) IN	IN 79-93	1	0.718	0.716	0.715
					IN 79-93	2			
					IN 94-104	1			
					IN 94-104	2			
					IN 105-106	1			
					IN 105-106	2			
					Tumor rate: 14% in CTL - Total	-			
LIVER	(1800)	)HEPATOCELLULA	(180032)	) IN	IN 94-104	1	0.725	0.719	0.719
					IN 94-104	2			
					IN 105-106	1			
					IN 105-106	2			
					Tumor rate: 3% in CTL - Total	-			
PANCREAS	(2000)	)ISLET-CELL AD	(200008)	) IN	IN 105-106	1	0.345	0.326	0.326
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
URINARY BL	(2300)	)TRANSITIONAL	(230011)	) IN	IN 0-78	1	0.625	0.675	0.675

(Continued)

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#--] [---+] [---\*]  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
				IN 0-78	2	(b)(4)-C/G		
				Tumor rate: <1% in CTL - Total	-			
OVARIES	(3200)	)GRANULOSA-THE	(320010)	IN 79-93	1			
				IN 79-93	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 2% in CTL - Total	-			
OVARIES	(3200)	)LUTEOMA	(320011)	IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-		[---+]	[---+]
OVARIES	(3200)	)GRANULOSA-THE	(320012)	IN 105-106	1	0.393	0.325	0.325
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-			
OVARIES	(3200)	)MESOTHELIOMA	(320018)	IN 105-106	1	0.200	0.178	0.178
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-			
UTERUS	(3400)	)LEIOMYOMA (C)	(160105)	IN 105-106	1	0.199	0.039*	0.039*
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-		[---*]	[---*]
UTERUS	(3400)	)LEIOMYOSARCOM	(160302)	IN 105-106	1	0.602	0.679	0.680
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-			
UTERUS	(3400)	)ENDOMETRIAL S	(340002)	IN 0-78	1	0.708	0.705	0.705
				IN 0-78	2			
				IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 12% in CTL - Total	-			
UTERUS	(3400)	)MALIGNANT SCH	(340007)	MX FA 80	1	1.000	0.807	0.807
				FA 80	2			
				Tumor rate: 1% in CTL - Total	-			
UTERUS	(3400)	)ENDOMETRIAL A	(340013)	MX IN 105-106	1	0.199	0.188	0.188
				IN 105-106	2			
				FA 76	1			
				FA 76	2			
				FA 93	1			
				FA 93	2			

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(Continued)

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)

Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols {^---} {-&amp;---} {---+} {---+} ^ &amp; + \*

Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$ 

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
				FA 96	1			
				FA 96	2			
				FA 103	1			
				FA 103	2			
				FA 105	1			
				FA 105	2			
				Tumor rate: 4% in CTL - Total	-			
VAGINA	(3500	)MALIGNANT SCH(340007	) MX	IN 105-106	1	0.410	0.273	0.273
				IN 105-106	2			
				FA 91	1			
				FA 91	2			
				Tumor rate: 1% in CTL - Total	-			
PITUITARY	(4100	)ADENOMA, PARS(410006	) MX	IN 79-93	1	0.014+	0.013+	0.013+
				IN 79-93	2			
				IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				FA 55	1			
				FA 55	2			
				FA 56	1			
				FA 56	2			
				FA 62	1			
				FA 62	2			
				FA 73	1			
				FA 73	2			
				FA 75	1			
				FA 75	2			
				FA 79	1			
				FA 79	2			
				FA 88	1			
				FA 88	2			
				FA 89	1			
				FA 89	2			
				FA 90	1			
				FA 90	2			
				FA 94	1			
				FA 94	2			
				FA 95	1			
				FA 95	2			
				FA 96	1			
				FA 96	2			
				FA 98	1			
				FA 98	2			
				FA 101	1			
				FA 101	2			
				FA 103	1			

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APPEARS THIS WAY ON ORIGINAL

(Continued)

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#---] [---+] [---\*] ^ # + \*  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<.005 P<.01 P<.025 P<.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
				FA 103	2			
				FA 104	1			
				FA 104	2			
				Tumor rate: 51% in CTL - Total	-			
						[---+]	[---+]	[---+]
THYROID GL(4200	)	FOLLICULAR CE(420002	)	IN IN 79-93	1	0.995	0.970	0.970
				IN 79-93	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 5% in CTL - Total	-			
THYROID GL(4200	)	C-CELL ADENOM(420010	)	IN IN 79-93	1	0.919	0.916	0.916
				IN 79-93	2			
				IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 14% in CTL - Total	-			
THYROID GL(4200	)	C-CELL CARCIN(420013	)	IN IN 79-93	1	0.782	0.783	0.783
				IN 79-93	2			
				IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
THYROID GL(4200	)	FOLLICULAR CE(420015	)	IN IN 94-104	1	0.528	0.374	0.374
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-			
PARATHYROI(4300	)	ADENOMA (C) (430006	)	IN IN 105-106	1	0.843	0.826	0.826
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
ADRENAL CO(4401	)	CARCINOMA (C)(280003	)	MX IN 105-106	1	0.199	0.039*	0.039*
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-		[---*]	[---*]
ADRENAL CO(4401	)	ADENOMA (C) (430006	)	IN IN 94-104	1	0.051	0.023+	0.023+
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: <1% in CTL - Total	-		[---+]	[---+]
ADRENAL ME(4402	)	PHEOCHROMOCYT(440205	)	IN IN 0-78	1	0.588	0.593	0.593
				IN 0-78	2			

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(Continued)

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note:

For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-&---] [---+] [---\*] ^ & + \*  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<0.005 P<0.01 P<0.025 P<0.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
				IN 79-93	1			
				IN 79-93	2			
				IN 105-106	1			
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
HEMOLYMPHO(4500		)MALIGNANT LYM(450001	) MX	IN 79-93	1	0.636	0.629	0.629
				IN 79-93	2			
				IN 94-104	1			
				IN 94-104	2			
				IN 105-106	1			
				IN 105-106	2			
				FA 80	1			
				FA 80	2			
				Tumor rate: 7% in CTL - Total	-			
HEMOLYMPHO(4500		)HISTIOCYTIC S(450003	) FA	FA 106	1	1.000	0.805	0.806
				FA 106	2			
				Tumor rate: 1% in CTL - Total	-			
SPLEEN (4600		)HEMANGIOSARCO(460014	) IN	IN 105-106	1	0.632	0.613	0.614
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
SPLEEN (4600		)HEMANGIOMA (C(460018	) IN	IN 105-106	1	1.000	0.805	0.805
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
LYMPH NODE(5100		)HISTIOCYTIC S(010010	) IN	IN 105-106	1	1.000	0.805	0.805
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
MESENT. LY(5104		)HEMANGIOMA (C(460018	) IN	IN 105-106	1	0.942	0.937	0.937
				IN 105-106	2			
				Tumor rate: 13% in CTL - Total	-			
MAMMARY GL(5600		)HISTIOCYTIC S(010010	) IN	IN 105-106	1	1.000	0.805	0.805
				IN 105-106	2			
				Tumor rate: 1% in CTL - Total	-			
MAMMARY GL(5600		)CARCINOMA (C)(280003	) MX	IN 105-106	1	0.517	0.514	0.514
				IN 105-106	2			
				FA 90	1			
				FA 90	2			
				FA 98	1			
				FA 98	2			
				FA 103	1			
				FA 103	2			
				Tumor rate: 3% in CTL - Total	-			

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Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)  
 For missing Tumor-Caused-Death set INCIDENTAL

Note: Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-\$--] [---+] [---\*] ^ \$ + \*  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<0.005 P<0.01 P<0.025 P<0.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
MAMMARY GL(5600		)ADENOMA (C)	(430006	) IN	IN 105-106	1	0.273	0.215	0.215
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
MAMMARY GL(5600		)FIBROADENOMA (560006	) MX	IN	IN 0-78	1	1.000	0.999	0.999
					IN 0-78	2			
					IN 79-93	1			
					IN 79-93	2			
					IN 94-104	1			
					IN 94-104	2			
					IN 105-106	1			
					IN 105-106	2			
					FA 48	1			
					FA 48	2			
					FA 56	1			
					FA 56	2			
					FA 68	1			
					FA 68	2			
					FA 77	1			
					FA 77	2			
					FA 85	1			
					FA 85	2			
					FA 88	1			
					FA 88	2			
					FA 93	1			
					FA 93	2			
					FA 101	1			
					FA 101	2			
					Tumor rate: 29% in CTL - Total	-			
SKIN (5700		)HISTIOCYTIC S(010010	) IN	IN	IN 105-106	1	1.000	0.805	0.805
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
SKIN (5700		)SQUAMOUS CELL(090038	) MX	IN	IN 105-106	1	0.398	0.262	0.262
					IN 105-106	2			
					FA 104	1			
					FA 104	2			
					Tumor rate: 1% in CTL - Total	-			
SKIN (5700		)HEMANGIOSARCO(460014	) IN	IN	IN 105-106	1	1.000	0.805	0.805
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total	-			
SKIN (5700		)FIBROMA (570010	) MX	IN	IN 105-106	1	0.844	0.832	0.832
					IN 105-106	2			
					FA 91	1			
					FA 91	2			
					Tumor rate: 1% in CTL - Total	-			

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APPEARS THIS WAY ON ORIGINAL



(Continued)

Analysis of Carcinogenic Potential in Female Rat  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: February 26, 1997 (16:51)  
 Source: c:\arat\xrod.txt

Dose Levels Included: CNTL1 CNTL2 LOW MED HIGH (0 0 150 500 1000)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#--] [---+] [---\*] ^ \* +  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES			
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT	
SKIN	(5700	)KERATOACANTHO	(570011	) IN	IN 105-106	1	1.000	0.805	0.805
					IN 105-106	2			
					Tumor rate: 1% in CTL - Total				
SKIN	(5700	)ZYMBAL'S GLAN	(570032	) FA	FA 93	1	0.421	0.283	0.284
					FA 93	2			
					FA 100	1			
					FA 100	2			
					Tumor rate: <1% in CTL - Total				
ADIPOSE TI	(6400	)LIPOSARCOMA ((	(570018	) IN	IN 94-104	1	0.189	0.114	0.114
					IN 94-104	2			
					IN 105-106	1			
					IN 105-106	2			
					Tumor rate: <1% in CTL - Total				
BODY CAVIT	(6800	)MALIGNANT SCH	(340007	) MX	FA 71	1	1.000	0.806	0.806
					FA 71	2			
					Tumor rate: 1% in CTL - Total				
BODY CAVIT	(6800	)PARAGANGLIOMA	(680005	) IN	IN 94-104	1	0.348	0.111	0.111
					IN 94-104	2			
					Tumor rate: <1% in CTL - Total				

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# **Test of Dose-Response Positive Linear Trend in Male Mice**

Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Ted Guo, PH.D, CDER/FDA

Run Date & Time: March 7, 1997 (10:15)

Source: c:\amouse\xrod.txt

Dose Levels Included: CTRL CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#--] [--+-] [---\*] ^ # + \*  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
BRAIN	(0100)	)MALIGNANT SCH(010012	)	MX	IN 79-91	1	0.680	0.770	0.771
					IN 79-91	2			
					Tumor rate: <1% in CTL - Total	-			
HEART	(0400)	)HISTIOCYTIC S(040015	)	MX	FA 101	1	0.140	0.102	0.102
					FA 101	2			
					FA 102	1			
					FA 102	2			
					Tumor rate: <1% in CTL - Total	-			
LUNG	(0900)	)HISTIOCYTIC S(040015	)	MX	IN 79-91	1	0.232	0.258	0.259
					IN 79-91	2			
					FA 101	1			
					FA 101	2			
					FA 102	1			
					FA 102	2			
					Tumor rate: <1% in CTL - Total	-			
LUNG	(0900)	)ALVEOLAR/BRON(090003	)	IN	IN 0-52	1	0.977	0.977	0.977
					IN 0-52	2			
					IN 53-78	1			
					IN 53-78	2			
					IN 79-91	1			
					IN 79-91	2			
					IN 92-104	1			
					IN 92-104	2			
					IN 105-105	1			
					IN 105-105	2			
					Tumor rate: 37% in CTL - Total	-			
LUNG	(0900)	)ALVEOLAR/BRON(090012	)	MX	IN 0-52	1	0.926	0.924	0.924
					IN 0-52	2			
					IN 53-78	1			
					IN 53-78	2			
					IN 79-91	1			
					IN 79-91	2			
					IN 92-104	1			
					IN 92-104	2			
					IN 105-105	1			
					IN 105-105	2			
					FA 74	1			
					FA 74	2			
					FA 78	1			
					FA 78	2			
					FA 81	1			
					FA 81	2			
					FA 83	1			
					FA 83	2			
					FA 85	1			

(Continued)

Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xtrod.txt

Dose Levels Included: CTRL CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)  
 Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [-] [-\*] [-\*+] [-\*+] ^ % + \*  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
				FA 85	2			
				FA 89	1			
				FA 89	2			
				FA 90	1			
				FA 90	2			
				FA 93	1			
				FA 93	2			
				FA 96	1			
				FA 96	2			
				FA 98	1			
				FA 98	2			
				FA 99	1			
				FA 99	2			
				FA 101	1			
				FA 101	2			
				Tumor rate: 31% in CTL - Total	-			
TONGUE	(1100)	MASTOCYTOMA (110014)	IN	IN 92-104	1	0.513	0.561	0.561
				IN 92-104	2			
				Tumor rate: <1% in CTL - Total	-			
STOMACH	(1500)	HISTIOCYTIC S(040015)	MX	FA 81	1	0.612	0.722	0.722
				FA 81	2			
				FA 104	1			
				FA 104	2			
				Tumor rate: <1% in CTL - Total	-			
STOMACH	(1500)	ADENOMA (ADEN(150005))	IN	IN 79-91	1	0.140	0.137	0.137
				IN 79-91	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: 1% in CTL - Total	-			
STOMACH	(1500)	SQUAMOUS CELL(150023)	IN	IN 92-104	1	0.750	0.782	0.783
				IN 92-104	2			
				Tumor rate: <1% in CTL - Total	-			
DUODENUM	(1601)	HISTIOCYTIC S(040015)	MX	IN 92-104	1	0.513	0.561	0.561
				IN 92-104	2			
				Tumor rate: <1% in CTL - Total	-			
DUODENUM	(1601)	ADENOMA (C) (160112)	IN	IN 92-104	1	0.443	0.554	0.554
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: <1% in CTL - Total	-			
CECUM	(1701)	ADENOCARCINOM(170111)	IN	IN 92-104	1	0.750	0.782	0.783
				IN 92-104	2			

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrod.txt

Dose Levels Included: CTRL CTRL2 LOW MED HIGH MAXI (0 0 25 375 750 1500)  
 For missing Tumor-Caused-Death set INCIDENTAL

Note: Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-#--] [---+] [---\*]  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.05$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW	TABLE	P VALUES		
							EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
Tumor rate: <1% in CTL - Total -									
LIVER	(1800	)HISTIOCYTIC S(040015	) MX	IN 79-91	1		0.668	0.715	0.715
				IN 79-91	2				
				IN 92-104	1				
				IN 92-104	2				
				FA 101	1				
				FA 101	2				
Tumor rate: <1% in CTL - Total -									
LIVER	(1800	)HEMANGIOMA (C(160212	) IN	IN 92-104	1		0.339	0.213	0.214
				IN 92-104	2				
				IN 105-105	1				
				IN 105-105	2				
Tumor rate: 1% in CTL - Total -									
LIVER	(1800	)HEMANGIOSARCO(180003	) MX	IN 79-91	1		0.203	0.209	0.209
				IN 79-91	2				
				IN 92-104	1				
				IN 92-104	2				
				IN 105-105	1				
				IN 105-105	2				
				FA 82	1				
				FA 82	2				
				FA 83	1				
				FA 83	2				
				FA 85	1				
				FA 85	2				
				FA 93	1				
				FA 93	2				
				FA 100	1				
				FA 100	2				
				FA 104	1				
				FA 104	2				
Tumor rate: 4% in CTL - Total -									
LIVER	(1800	)HEPATOCELLULA(180017	) IN	IN 53-78	1		0.222	0.216	0.216
				IN 53-78	2				
				IN 92-104	1				
				IN 92-104	2				
				IN 105-105	1				
				IN 105-105	2				
Tumor rate: 5% in CTL - Total -									
LIVER	(1800	)HEPATOCELLULA(180023	) MX	IN 92-104	1		0.274	0.247	0.248
				IN 92-104	2				
				IN 105-105	1				
				IN 105-105	2				
				FA 82	1				

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrcd.txt

Dose Levels Included: CTR1 CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)  
 For missing Tumor-Caused-Death set INCIDENTAL

Note: Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-\*--] [---+] [---\*] ^ \*  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<0.005 P<0.01 P<0.025 P<0.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE	INTERVAL	ROW	TABLE	P VALUES		
								EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
					FA 82	2				
					FA 101	1				
					FA 101	2				
					Tumor rate: 3% in CTL - Total	-				
LIVER	(1800)	)HEPATOBLASTOM(180030	) FA	FA 62	1			0.164	0.025+	0.025+
					FA 62	2				
					Tumor rate: <1% in CTL - Total	-				
									[---*]	[---*]
GALLBLADDE	(1900)	)HISTIOCYTIC S(040015	) MX	FA 104	1			0.481	0.530	0.530
					FA 104	2				
					Tumor rate: <1% in CTL - Total	-				
PANCREAS	(2000)	)HISTIOCYTIC S(040015	) MX	IN 79-91	1			0.295	0.310	0.310
					IN 79-91	2				
					IN 92-104	1				
					IN 92-104	2				
					FA 100	1				
					FA 100	2				
					FA 104	1				
					FA 104	2				
					Tumor rate: <1% in CTL - Total	-				
PANCREAS	(2000)	)ISLET-CELL AD(200007	) IN	IN 53-78	1			0.786	0.765	0.765
					IN 53-78	2				
					IN 105-105	1				
					IN 105-105	2				
					Tumor rate: 1% in CTL - Total	-				
PANCREAS	(2000)	)MASTOCYTOMA, (200015	) IN	IN 79-91	1			1.000	0.785	0.785
					IN 79-91	2				
					Tumor rate: 1% in CTL - Total	-				
KIDNEYS	(2100)	)HISTIOCYTIC S(040015	) MX	IN 79-91	1			0.623	0.724	0.724
					IN 79-91	2				
					FA 101	1				
					FA 101	2				
					Tumor rate: <1% in CTL - Total	-				
KIDNEYS	(2100)	)TUBULAR CARCI(210020	) IN	IN 105-105	1			1.000	0.780	0.780
					IN 105-105	2				
					Tumor rate: 1% in CTL - Total	-				
URINARY BL	(2300)	)NEOPLASTIC MA(230005	) IN	IN 79-91	1			0.320	0.250	0.250
					IN 79-91	2				
					Tumor rate: <1% in CTL - Total	-				
URINARY BL	(2300)	)LEIOMYOSARCOM(230017	) MX	IN 105-105	1			0.558	0.540	0.540
					IN 105-105	2				

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrod.txt

Dose Levels Included: CTRL CTR2 LOW MED HIGH MAX1 (0 0 25 375 750 1500)

Note: For missing Tumor-Caused-Death set INCIDENTAL  
 Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-\*--] [---+] [---\*] ^ \* + \*  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
				Tumor rate: 1% in CTL - Total	-			
TESTES	(2500)	)HEMANGIOMA (C(160212	)	IN IN 105-105	1	1.000	0.780	0.780
				IN 105-105	2			
				Tumor rate: 1% in CTL - Total	-			
TESTES	(2500)	)LEYDIG CELL T(250006	)	IN IN 92-104	1	0.876	0.857	0.858
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: 4% in CTL - Total	-			
TESTES	(2500)	)LEYDIG CELL T(250012	)	IN IN 79-91	1	1.000	0.785	0.785
				IN 79-91	2			
				Tumor rate: 1% in CTL - Total	-			
EPIDIDYDYMID(2600		)HISTIOCYTIC S(040015	)	MX FA 104	1	0.481	0.530	0.530
				FA 104	2			
				Tumor rate: <1% in CTL - Total	-			
EPIDIDYDYMID(2600		)LEYDIG CELL T(260006	)	IN IN 53-78	1	0.405	0.318	0.319
				IN 53-78	2			
				Tumor rate: <1% in CTL - Total	-			
PROSTATE G(2700		)HISTIOCYTIC S(040015	)	MX IN 92-104	1	0.513	0.561	0.561
				IN 92-104	2			
				Tumor rate: <1% in CTL - Total	-			
PROSTATE G(2700		)ADENOCARCINOM(160110	)	MX IN 105-105	1	1.000	0.780	0.780
				IN 105-105	2			
				Tumor rate: 1% in CTL - Total	-			
COAGULATIN(2701		)HISTIOCYTIC S(040015	)	MX FA 104	1	0.481	0.530	0.530
				FA 104	2			
				Tumor rate: <1% in CTL - Total	-			
COAGULATIN(2701		)ADENOMA (C) (160112	)	IN IN 105-105	1	1.000	0.780	0.780
				IN 105-105	2			
				Tumor rate: 1% in CTL - Total	-			
COAGULATIN(2701		)GRANULAR CELL(270109	)	IN IN 105-105	1	0.585	0.766	0.766
				IN 105-105	2			
				Tumor rate: <1% in CTL - Total	-			
SEMINAL VE(2800		)HISTIOCYTIC S(040015	)	MX IN 92-104	1	0.674	0.723	0.723
				IN 92-104	2			
				FA 81	1			
				FA 81	2			
				FA 100	1			

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrod.txt

Dose Levels Included: CTR1 CTR2 LOW MED HIGH MAX1 (0 0 25 375 750 1500)  
 For missing Tumor-Caused-Death set INCIDENTAL

Note: Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [-] [-] [-] [-]  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYME- TCTIC	CONTINU CORRECT
					FA 100				
					Tumor rate: <1% in CTL - Total				
SEMINAL VE(2800)		HEMANGIOMA (C(160212	)	IN	IN 105-105 1		0.585	0.766	0.766
					IN 105-105 2				
					Tumor rate: <1% in CTL - Total				
SEMINAL VE(2800)		LEIOMYOSARCOM(230017	)	MX	IN 53-78 1		1.000	0.932	0.932
					IN 53-78 2				
					IN 92-104 1				
					IN 92-104 2				
					FA 96 1				
					FA 96 2				
					Tumor rate: 3% in CTL - Total				
SEMINAL VE(2800)		GRANULAR CELL(270109	)	IN	IN 92-104 1		0.998	0.974	0.974
					IN 92-104 2				
					IN 105-105 1				
					IN 105-105 2				
					Tumor rate: 5% in CTL - Total				
SEMINAL VE(2800)		UNDIFFERENTIA(280019	)	IN	IN 105-105 1		1.000	0.780	0.780
					IN 105-105 2				
					Tumor rate: 1% in CTL - Total				
BULBOURETH(3001)		LEIOMYOSARCOM(230017	)	MX	IN 105-105 1		0.163	0.024+	0.024+
					IN 105-105 2				
					Tumor rate: <1% in CTL - Total				
BULBOURETH(3001)		ADENOMA, PAPL(300110	)	IN	IN 105-105 1		1.000	0.780	0.780
					IN 105-105 2				
					Tumor rate: 1% in CTL - Total				
PITUITARY (4100)		ADENOMA, PARS(410001	)	IN	IN 79-91 1		0.140	0.018-	0.018+
					IN 79-91 2				
					Tumor rate: <1% in CTL - Total				
THYROID GL(4200)		HISTIOCYTIC S(040015	)	MX	IN 79-91 1		0.660	0.771	0.771
					IN 79-91 2				
					Tumor rate: <1% in CTL - Total				
THYROID GL(4200)		FOLLICULAR CE(420013	)	IN	IN 79-91 1		0.671	0.709	0.709
					IN 79-91 2				
					IN 92-104 1				
					IN 92-104 2				
					Tumor rate: 1% in CTL - Total				
PAR-THYROID(4300)		ADENOMA (C) (160112	)	IN	IN 92-104 1		0.390	0.377	0.377
					IN 92-104 2				

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\mouse\xrod.txt

Dose Levels Included: CTR1 CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-#---] [---+] [---\*]  
 Represent 0<P<0.005 0.005<=P<0.01 0.01<=P<0.025 0.025<=P<0.05 P<.005 P<.01 P<.025 P<.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: <1% in CTL - Total	-			
ADRENAL CO(4401		)HISTIOCYTIC S(040015	) MX	IN 79-91	1	0.613	0.716	0.716
				IN 79-91	2			
				FA 104	1			
				FA 104	2			
				Tumor rate: <1% in CTL - Total	-			
ADRENAL CO(4401		)CARCINOMA/TYP(440101	) MX	IN 105-105	1	0.372	0.407	0.407
				IN 105-105	2			
				FA 98	1			
				FA 98	2			
				Tumor rate: 1% in CTL - Total	-			
ADRENAL CO(4401		)CARCINOMA/TYP(440104	) IN	IN 79-91	1	0.734	0.778	0.778
				IN 79-91	2			
				IN 92-104	1			
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: 1% in CTL - Total	-			
ADRENAL CO(4401		)ADENOMA, TYPE(440118	) IN	IN 53-78	1	0.552	0.547	0.546
				IN 53-78	2			
				IN 79-91	1			
				IN 79-91	2			
				IN 92-104	1			
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: 19% in CTL - Total	-			
ADRENAL CO(4401		)ADENOMA, TYPE(440120	) IN	IN 105-105	1	1.000	0.863	0.863
				IN 105-105	2			
				Tumor rate: 2% in CTL - Total	-			
ADRENAL CO(4401		)ADENOMA (CORT(440130	) IN	IN 92-104	1	0.868	0.902	0.902
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				Tumor rate: <1% in CTL - Total	-			
ADRENAL ME(4402		)PHEOCHROMOCYT(440207	) IN	IN 92-104	1	0.513	0.561	0.561
				IN 92-104	2			
				Tumor rate: <1% in CTL - Total	-			
SYSTEMIC N(4500		)MALIGNANT LYM(450001	) MX	IN 0-52	1	0.645	0.652	0.652

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)

Source: c:\amouse\xrod.txt

Dose Levels Included: CTRL CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols [^---] [-\*---] [---+] [---\*] ^ \* + \*

Represent 0&lt;P&lt;0.005 0.005&lt;=P&lt;0.01 0.01&lt;=P&lt;0.025 0.025&lt;=P&lt;0.05 P&lt;.005 P&lt;.01 P&lt;.025 P&lt;.05

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYME- TOTIC	CONTINU CORRECT
				IN 0-52	2			
				IN 53-78	1			
				IN 53-78	2			
				IN 79-91	1			
				IN 79-91	2			
				IN 92-104	1			
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				FA 41	1			
				FA 41	2			
				FA 52	1			
				FA 52	2			
				FA 55	1			
				FA 55	2			
				FA 65	1			
				FA 65	2			
				FA 71	1			
				FA 71	2			
				FA 72	1			
				FA 72	2			
				FA 80	1			
				FA 80	2			
				FA 81	1			
				FA 81	2			
				FA 82	1			
				FA 82	2			
				FA 83	1			
				FA 83	2			
				FA 84	1			
				FA 84	2			
				FA 85	1			
				FA 85	2			
				FA 88	1			
				FA 88	2			
				FA 91	1			
				FA 91	2			
				FA 93	1			
				FA 93	2			
				FA 94	1			
				FA 94	2			
				FA 96	1			
				FA 96	2			
				FA 98	1			
				FA 98	2			
				FA 101	1			
				FA 101	2			
				FA 102	1			
				FA 102	2			

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(Continued)

Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrod.txt

Dose Levels Included: CTR1 CTR2 LOW MED HIGH MAXI (0 0\*25 375 750 1500)  
 Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-\*--] [---+] [---\*] ^ % + \*  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.05$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP- TOTIC	CONTINU CORRECT
				FA 104	1			
				FA 104	2			
				Tumor rate: 32% in CTL - Total	-			
SYSTEMIC N(4500)		HISTIOCYTIC S(450002)		FA 81	1	0.329	0.351	0.351
				FA 81	2			
				FA 100	1			
				FA 100	2			
				FA 101	1			
				FA 101	2			
				FA 102	1			
				FA 102	2			
				FA 104	1			
				FA 104	2			
				Tumor rate: <1% in CTL - Total	-			
SYSTEMIC N(4500)		MAST CELL TUM(450003)		MX IN 92-104	1	0.088	0.038*	0.038*
				IN 92-104	2			
				IN 105-105	1			
				IN 105-105	2			
				FA 94	1			
				FA 94	2			
				Tumor rate: 1% in CTL - Total	-			
							[---*]	[---*]
SYSTEMIC N(4500)		MYELOID LEUKE(450004)		MX IN 92-104	1	0.507	0.438	0.438
				IN 92-104	2			
				FA 103	1			
				FA 103	2			
				Tumor rate: 2% in CTL - Total	-			
SPLEEN	(4600)	HISTIOCYTIC S(040015)		MX FA 81	1	0.622	0.729	0.729
				FA 81	2			
				FA 101	1			
				FA 101	2			
				Tumor rate: <1% in CTL - Total	-			
SPLEEN	(4600)	HEMANGIOSARCO(180003)		MX FA 96	1	1.000	0.789	0.789
				FA 96	2			
				Tumor rate: 1% in CTL - Total	-			
THYMUS	(5000)	HISTIOCYTIC S(040015)		MX IN 92-104	1	0.301	0.321	0.321
				IN 92-104	2			
				FA 81	1			
				FA 81	2			
				FA 101	1			
				FA 101	2			
				FA 102	1			
				FA 102	2			
				Tumor rate: <1% in CTL - Total	-			

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)

Source: c:\amouse\xrod.txt

Dose Levels Included: CTRL CTR2 LOW MED HIGH MAXI (0 0 25 375 750 1500)

Note: For missing Tumor-Caused-Death set INCIDENTAL

Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)

Symbols (^---) [-#--] [---+] [---+]

Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TIME TYPE INTERVAL	ROW TABLE	P VALUES		
						EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
LYMPH NODE(5100)		)HISTIOCYTIC S(040015		) MX IN 79-91	1	0.687	0.709	0.709
					IN 79-91 2			
					IN 92-104 1			
					IN 92-104 2			
					FA 104 1			
					FA 104 2			
					Tumor rate: <1% in CTL - Total -			
MESENT. LY(5104)		)HISTIOCYTIC S(040015		) MX IN 79-91	1	0.680	0.770	0.771
					IN 79-91 2			
					Tumor rate: <1% in CTL - Total -			
MESENT. LY(5104)		)HEMANGIOMA (C(160212		) IN IN 53-78	1	0.369	0.382	0.382
					IN 53-78 2			
					IN 92-104 1			
					IN 92-104 2			
					IN 105-105 1			
					IN 105-105 2			
					Tumor rate: 2% in CTL - Total -			
MESENT. LY(5104)		)HEMANGIOSARCO(180003		) MX IN 79-91	1	1.000	0.785	0.785
					IN 79-91 2			
					Tumor rate: 1% in CTL - Total -			
MANDIB. LYM(5108)		)HISTIOCYTIC S(040015		) MX FA 81	1	0.653	0.773	0.773
					FA 81 2			
					Tumor rate: <1% in CTL - Total -			
HARDERIAN (5400)		)ADENOCARCINOM(160110		) MX IN 79-91	1	0.503	0.525	0.525
					IN 79-91 2			
					IN 92-104 1			
					IN 92-104 2			
					IN 105-105 1			
					IN 105-105 2			
					FA 96 1			
					FA 96 2			
					Tumor rate: 2% in CTL - Total -			
HARDERIAN (5400)		)ADENOMA (C) (160112		) IN IN 53-78	1	0.319	0.306	0.307
					IN 53-78 2			
					IN 92-104 1			
					IN 92-104 2			
					IN 105-105 1			
					IN 105-105 2			
					Tumor rate: 4% in CTL - Total -			
MAMMARY GL(5600)		)ADENOMA (C) (160112		) IN IN 92-104	1	0.750	0.782	0.783
					IN 92-104 2			
					Tumor rate: <1% in CTL - Total -			

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Analysis of Carcinogenic Potential in Male Mouse  
 Test of Dose-Response (Tumor) Positive Linear Trend  
 Run Date & Time: March 7, 1997 (10:15)  
 Source: c:\amouse\xrod.txt

Dose Levels Included: CTR1 CTR2 LOW MED HIGH MAX1 (0 0 25 375 750 1500)  
 For missing Tumor-Caused-Death set INCIDENTAL

Note: Tumor Type: IN: Incidental (nonfatal) to all, FA: Fatal to all, MX: Mixed (Fatal to some)  
 Symbols [^---] [-#---] [---+] [---\*]  
 Represent  $0 < P < 0.005$   $0.005 \leq P < 0.01$   $0.01 \leq P < 0.025$   $0.025 \leq P < 0.05$   $P < 0.005$   $P < 0.01$   $P < 0.025$   $P < 0.05$

ORGAN NAME	ORGAN CODE	TUMOR NAME	TUMOR CODE	TUMOR TYPE	TIME INTERVAL	ROW TABLE	P VALUES		
							EXACT PERMU	ASYMP-TOTIC	CONTINU CORRECT
SKIN/SUBCU(5700		)MALIGNANT SCH(010012		) MX	FA 66	1	0.495	0.541	0.542
					FA 66	2			
					Tumor rate: <1% in CTL - Total				
SKIN/SUBCU(5700		)HEMANGIOSARCO(180003		) MX	IN 105-105	1	0.163	0.024+	0.024+
					IN 105-105	2			
					Tumor rate: <1% in CTL - Total				
SKIN/SUBCU(5700		)SQUAMOUS CELL(570001		) FA	FA 70	1	1.000	0.788	0.788
					FA 70	2			
					Tumor rate: 1% in CTL - Total				
BONE/OTHER(5902		)OSTEOMA	(590203	) IN	IN 92-104	1	0.329	0.301	0.302
					IN 92-104	2			
					Tumor rate: <1% in CTL - Total				
BONE/OTHER(5902		)ODONTOMA	(590204	) IN	IN 92-104	1	1.000	0.795	0.796
					IN 92-104	2			
					Tumor rate: 1% in CTL - Total				
ADIPOSE TI(6400		)HISTIOCYTIC S(040015		) MX	IN 92-104	1	0.513	0.561	0.561
					IN 92-104	2			
					Tumor rate: <1% in CTL - Total				
ADIPOSE TI(6400		)LIPOMA	(640007	) IN	IN 92-104	1	0.339	0.213	0.214
					IN 92-104	2			
					IN 105-105	1			
					IN 105-105	2			
Tumor rate: 1% in CTL - Total		-							
ADIPOSE TI(6400		)SARCOMA, NOT (640008		) IN	IN 79-91	1	1.000	0.785	0.785
					IN 79-91	2			
					Tumor rate: 1% in CTL - Total				
EYES (6500		)HISTIOCYTIC S(040015		) MX	FA 101	1	0.493	0.546	0.547
					FA 101	2			
					Tumor rate: <1% in CTL - Total				
BODY CAVIT(6800		)HISTIOCYTIC S(040015		) MX	IN 79-91	1	0.680	0.770	0.771
					IN 79-91	2			
					Tumor rate: <1% in CTL - Total				
TAIL (7400		)MALIGNANT SCH(010012		) MX	IN 105-105	1	0.472	0.533	0.534
					IN 105-105	2			
					Tumor rate: <1% in CTL - Total				

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